Commonwealth of Massachusetts
Executive Office of Energy & Environmental Affairs

Department of Environmental Protection

Southeast Regional Office • 20 Riverside Drive, Lakeville MA 02347 • 508-946-2700

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February 1, 2017

Mr. Frank G. Fives
V.P. of Manufacturing
Siemens Healthcare Diagnostics, Inc.
333 Coney Street
Walpole, MA 02032

RE: WALPOLE
Transmittal No.: X272951
Application No.: SE-16-020
Class: *SM-50*
FMF No.: 317978
AIR QUALITY PLAN APPROVAL

Dear Mr. Fives:

The Massachusetts Department of Environmental Protection ("MassDEP"), Bureau of Air and Waste, has reviewed your Limited Plan Application ("Application") listed above. This Application concerns the proposed operation of production equipment at your diagnostic test kit and supporting equipment manufacturing facility located at 333 Coney Street in Walpole, Massachusetts ("Facility").

The Application was submitted in accordance with 310 CMR 7.02 Plan Approval and Emission Limitations as contained in 310 CMR 7.00 "Air Pollution Control," regulations adopted by MassDEP pursuant to the authority granted by Massachusetts General Laws, Chapter 111, Section 142 A-J, Chapter 21C, Section 4 and 6, and Chapter 21E, Section 6. MassDEP's review of your Application has been limited to air pollution control regulation compliance and does not relieve you of the obligation to comply with any other regulatory requirements.

MassDEP has determined that the Application is administratively and technically complete and that the Application is in conformance with the Air Pollution Control regulations and current air pollution control engineering practice, and hereby grants this **Plan Approval** for said Application, as submitted, subject to the conditions listed below.

Please review the entire Plan Approval, as it stipulates the conditions with which the Facility owner/operator ("Permittee") must comply in order for the Facility to be operated in compliance with this Plan Approval.

1. DESCRIPTION OF FACILITY AND APPLICATION

Siemens Healthcare Diagnostics (Siemens) owns and operates a medical device manufacturing and research and development facility at 333 Coney Street in Walpole, Massachusetts. The facility develops and manufactures immunodiagnostic test kits, nucleic acid diagnostic test kits, and blood gas sensors. The facility currently occupies approximately 6.5 acres and is part of a larger 81-acre parcel of land. The Siemens facility is comprised of five interconnected buildings, as well as supporting infrastructure and associated ancillary equipment including existing natural gas fired boilers, natural gas fired water heaters, and diesel fired emergency generator engines that are not addressed in this application. The Siemens facility is an area source of Hazardous Air Pollutants (HAP) as listed in the 1990 Clean Air Act (CAA) Amendments, Section 112(b).

The Limited Plan Application for Process Emissions was submitted, as required by 310 CMR 7.02(4), to address additional emissions of Volatile Organic Compounds (VOC) and HAP resulting from a process modification which reduces drying time allowing for additional throughput, along with the addition of a second Terra Universal Incorporated (TUI), or equivalent, environmental chamber, for the existing Point of Care Sensor process at the facility. The Siemens manufacturing operations are primarily located in buildings 3 and 4 with some smaller scale manufacturing being conducted in buildings 1 and 2. The primary manufacturing departments currently consist of the following two operations: ImmunoAssay production and Point of Care (POC). The ImmunoAssay production can be further segmented into two processes, paramagnetic particle (PMP) production and ImmunoAssay mixing & filling. The Siemens facility is currently operating in accordance with a 310 CMR 7.02(11) 50% Emission Cap Approval issued on November 14, 2007, and operates non-exempt fuel utilization equipment in accordance with Plan Approval Nos. MBR-93-COM-006, MBR-93-COM-028 or 310 CMR 7.26 Industry Performance Standards.

Best Available Control Technology (BACT) for this application is defined in Table 2.

2. EMISSION UNIT (EU) IDENTIFICATION

Each Emission Unit (EU) identified in Table 1 is subject to and regulated by this Plan Approval:

Table 1

EU#	Description	Design Capacity	Pollution Control Device (PCD)
22	Paramagnetic Particle (PMP) production	1 batch (or campaign) per month	None
23	ImmunoAssay ReadyPack kit mixing and filling process	5,730 ReadyPack kits per hour	None
24	Point of Care sensor production	26,880 sensors per day	None

Table 1 Key:
EU# = Emission Unit Number
PCD = Pollution Control Device

3. APPLICABLE REQUIREMENTS

A. OPERATIONAL, PRODUCTION and EMISSION LIMITS

The Permittee is subject to, and shall not exceed the Operational, Production, and Emission Limits as contained in Table 2 below:

Table 2

EU#	Operational / Production Limit	Air Contaminant	Emission Limit
22	1. The Permittee shall limit the methanol consumed in the PMP production to 0.17 tons per month. (Note 1)	VOC and HAP (individual)	0.17 TPM
	2. The Permittee shall limit the methanol consumed in the PMP production to 2.09 tons per consecutive 12 month period. (Note 1)		2.09 TPY
23	3. The Permittee shall limit the VOC consumed in the mixing and filling of ImmunoAssy ReadyPack kits to 0.47 tons per month. (Note 2)	VOC	0.47 TPM
	4. The Permittee shall limit the VOC consumed in the mixing and filling of ImmunoAssy ReadyPack kits to 5.61 tons per consecutive 12 month period. (Note 2)		5.61 TPY
	5. The Permittee shall limit the maximum individual HAP consumed in the mixing and filling of ImmunoAssy ReadyPack kits to 0.15 tons per month. (Note 2)	HAP (individual)	0.15 TPM
	6. The Permittee shall limit the maximum individual HAP consumed in the mixing and filling of ImmunoAssy ReadyPack kits to 1.75 tons per consecutive 12 month period. (Note 2)		1.75 TPY
	7. The Permittee shall limit the total HAP consumed in the mixing and filling of ImmunoAssy ReadyPack kits to 0.30 tons per month. (Note 2)	HAP (total)	0.30 TPM
	8. The Permittee shall limit the total HAP consumed in the mixing and filling of ImmunoAssy ReadyPack kits to 3.58 tons per consecutive 12 month period. (Note 2)		3.58 TPY
24	9. The Permittee shall limit the VOC consumed in the point of care sensor production to 0.07 tons per month. (Note 3)	VOC	0.07 TPM
	10. The Permittee shall limit the VOC consumed in the point of care sensor production to 0.80 tons per consecutive 12 month period. (Note 3)		0.80 TPY

Table 2

EU#	Operational / Production Limit	Air Contaminant	Emission Limit
24	11. The Permittee shall limit the maximum individual HAP consumed in the point of care sensor production to 0.01 tons per month. (Note 3)	HAP (individual)	0.01 TPM
	12. The Permittee shall limit the maximum individual HAP consumed in the point of care sensor production to 0.11 tons per consecutive 12 month period. (Note 3)		0.11 TPY
	13. The Permittee shall limit the total HAP consumed in the point of care sensor production to 0.02 tons per month. (Note 3)	HAP (total)	0.02 TPM
	14. The Permittee shall limit the total HAP consumed in the point of care sensor production to 0.23 tons per consecutive 12 month period. (Note 3)		0.23 TPY

Table 2 Notes:

Note 1 – Methanol consumed in the PMP production is assumed to be 25% of methanol used. The Permittee shall maintain monthly records of Methanol used and waste methanol shipped off site to determine actual methanol consumption and demonstrate compliance with this limitation.

Note 2 – VOC and HAP consumed in the mixing and filling of ImmunoAssay ReadyPack kits is assumed to be 10% for VOC and/or HAP chemicals that are product components and 100% for non-product component VOC and/or HAP chemicals. The Permittee shall maintain monthly records of VOC and/or HAP used and may use records of waste shipped off site to determine actual VOC and/or HAP consumption for non-product component VOC and/or HAP.

Note 3 – VOC and HAP consumed in the Point of Care sensor production process is assumed to be 100% of VOC and/or HAP used. The Permittee shall maintain monthly records of VOC and/or HAP used and may use records of waste shipped off site to determine actual VOC and/or HAP consumption.

Table 2 Key:

EU# = Emission Unit Number
HAP (individual) = maximum individual Hazardous Air Pollutant
HAP (total) = total Hazardous Air Pollutants
PMP = paramagnetic particle
TPM = tons per month
TPY = tons per consecutive12-month period
VOC = Volatile Organic Compound(s)

B. COMPLIANCE DEMONSTRATION

The Permittee is subject to, and shall comply with, the monitoring, testing, record keeping, and reporting requirements as contained in Tables 3, 4, and 5 below:

Table 3

EU#	Monitoring and Testing Requirements
22	1. The Permittee shall monitor consumption (by weight) of methanol each month to verify PMP production operational limitations in Table 2. Methanol consumption shall be methanol used less any documented waste methanol shipped off site.
23	2. The Permittee shall monitor consumption (by weight) of VOC and HAP as contained in process materials each month to verify ImmunoAssay ReadyPack kit mixing and filling process operational limitations in Table 2. Consumption of VOC and HAP shall be VOC and HAP used less any documented waste VOC and HAP shipped off site, or in the case of product component VOC and HAP process material, 10%, by weight, of VOC and HAP used is to be considered "consumed".
24	3. The Permittee shall monitor consumption (by weight) of VOC and HAP containing materials each month to verify Point of Care sensor production operational limitations in Table 2. Consumption of VOC and HAP shall be VOC and HAP used less any documented waste VOC and HAP shipped off site.
Facility-wide	4. The Permittee shall monitor all operations to ensure sufficient information is available to comply with 310 CMR 7.12 Source Registration.
	5. If and when MassDEP requires it, the Permittee shall conduct emission testing in accordance with USEPA Reference Test Methods and regulation 310 CMR 7.13

Table 3 Key:
EU# = Emission Unit Number
HAP = Individual and Total Hazardous Air Pollutant(s)
VOC = Volatile Organic Compound(s)

Table 4

EU#	Record Keeping Requirements
22	1. The Permittee shall maintain monthly and consecutive twelve month records of the methanol consumed (by weight) in the PMP production process.
23	2. The Permittee shall maintain monthly and consecutive twelve month records of the VOC and HAP consumed (by weight) in the ImmunoAssay ReadyPack kit mixing and filling process.
24	3. The Permittee shall maintain monthly and consecutive twelve month records of the VOC and HAP consumed (by weight) in the Point of Care sensor production process.

Table 4

EU#	Record Keeping Requirements
Facility-wide	4. The Permittee shall maintain adequate records on-site to demonstrate compliance with all operational, production, and emission limits contained in Table 2 above. Records shall also include the actual emissions of air contaminant(s) emitted for each calendar month and for each consecutive twelve month period (current month plus prior eleven months). These records shall be compiled no later than the 15th day following each month. An electronic version of the MassDEP approved record keeping form, in Microsoft Excel format, can be downloaded at http://www.mass.gov/dep/air/approvals/aqforms.htm#report .
	5. The Permittee shall maintain records of monitoring and testing as required by Table 3.
	6. The Permittee shall maintain a copy of this Plan Approval, underlying Application and the most up-to-date SOMP for the EU(s) approved herein on-site.
	7. The Permittee shall maintain a record of routine maintenance activities performed on the approved EU(s), PCD(s) and monitoring equipment. The records shall include, at a minimum, the type or a description of the maintenance performed and the date and time the work was completed.
	8. The Permittee shall maintain a record of all malfunctions affecting air contaminant emission rates on the approved EU(s) and monitoring equipment. At a minimum, the records shall include: date and time the malfunction occurred; description of the malfunction; corrective actions taken; the date and time corrective actions were initiated and completed; and the date and time emission rates and monitoring equipment returned to compliant operation.
	9. The Permittee shall maintain records to ensure sufficient information is available to comply with 310 CMR 7.12 Source Registration.
	10. The Permittee shall maintain records required by this Plan Approval on-site for a minimum of five (5) years.
	11. The Permittee shall make records required by this Plan Approval available to MassDEP and USEPA personnel upon request.

Table 4 Key:
CMR = Code of Massachusetts Regulations
EU# = Emission Unit Number
HAP = Individual and Total Hazardous Air Pollutant(s)
MassDEP = Massachusetts Department of Environmental Protection
PCD = Pollution Control Device
PMP = paramagnetic particle
SOMP = Standard Operating and Maintenance Procedure
USEPA = United States Environmental Protection Agency
VOC = Volatile Organic Compound(s)

Table 5	
EU#	**Reporting Requirements**
Facility-wide	1. The Permittee shall submit to MassDEP all information required by this Plan Approval over the signature of a "Responsible Official" as defined in 310 CMR 7.00 and shall include the Certification statement as provided in 310 CMR 7.01(2)(c).
	2. The Permittee shall notify the Southeast Regional Office of MassDEP, BAW C&E Chief by telephone (508) 946-2878, or fax (508) 947-6557, as soon as possible, but no later than three (3) business days after discovery of an exceedance(s) of Table 2 requirements. A written report shall be submitted to BAW C&E Chief at MassDEP within ten (10) business days thereafter and shall include: identification of exceedance(s), duration of exceedance(s), reason for the exceedance(s), corrective actions taken, and action plan to prevent future exceedance(s).
	3. The Permittee shall report to MassDEP, in accordance with 310 CMR 7.12, all information as required by the Source Registration/Emission Statement Form. The Permittee shall note therein any minor changes (under 310 CMR 7.02(2)(e), 7.03, 7.26, etc.), which did not require Plan Approval.
	4. The Permittee shall provide a copy to MassDEP of any record required to be maintained by this Plan Approval within 30-days from MassDEP's request.
	5. The Permittee shall submit to MassDEP for approval a stack emission pretest protocol, at least 30 days prior to emission testing, for emission testing as defined in Table 3 Monitoring and Testing Requirements.
	6. The Permittee shall submit to MassDEP a final stack emission test results report, within 45 days after emission testing, for emission testing as defined in Table 3 Monitoring and Testing Requirements.

Table 5 Key:
BAW = Bureau of Air and Waste
C&E = Compliance and Enforcement
CMR = Code of Massachusetts Regulations
EU# = Emission Unit Number
MassDEP = Massachusetts Department of Environmental Protection

4. SPECIAL TERMS AND CONDITIONS

The Permittee is subject to, and shall comply with, the following special terms and conditions:

A. The Permittee shall comply with the Special Terms and Conditions as contained in Table 6 below:

Table 6	
EU#	**Special Terms and Conditions**
Facility-wide	1. The Permittee may reconcile the VOC and/or HAP contained in any hazardous waste shipped during a month when determining monthly emissions. The facility shall maintain hazardous waste disposal records and purchase records for VOC and HAP containing materials for this purpose. Such records shall verify the VOC and HAP quantity present in the waste being shipped if reconciling monthly emissions

Table 6	
EU#	**Special Terms and Conditions**
	2. The Permittee shall conduct all handling and transferring operations involving VOC and HAP containing solvents in a way that minimizes spills and releases of VOC and HAP.
	3. The Permittee shall ensure the containers of VOC and HAP containing solvents are in good condition and do not leak, and shall remain closed, except to add or remove material from them.
	4. This Approval letter and approved application shall supersede the Approval letter for LPA No. SE-16-005 issued on May 11, 2016, as well as the underlying application.
	5. Any prior Plan Approvals issued under 310 CMR 7.02 shall remain in effect unless specifically changed or superseded by this Plan Approval. The Facility shall not exceed the emission limits and shall comply with approved conditions specified in the prior Plan Approval(s) unless specifically altered by this Plan Approval.

Table 6 Key:
CMR = Code of Massachusetts Regulations
EU# = Emission Unit Number
HAP = Individual and Total Hazardous Air Pollutant(s)
LPA = Limited Plan Application
VOC = Volatile Organic Compound(s)

B. The Permittee shall install and use an exhaust stack, as required in Table 7, on each of the Emission Units that is consistent with good air pollution control engineering practice and that discharges so as to not cause or contribute to a condition of air pollution. Each exhaust stack shall be configured to discharge the gases vertically and shall not be equipped with any part or device that restricts the vertical exhaust flow of the emitted gases, including but not limited to rain protection devices known as "shanty caps" and "egg beaters." The Permittee shall install and utilize exhaust stacks with the following parameters, as contained in Table 7 below, for the Emission Units that are regulated by this Plan Approval:

Table 7				
EU#	**Stack Height Above Ground (feet)**	**Stack Inside Exit Dimensions (inches)**	**Stack Gas Exit Velocity Range (feet per minute)**	**Stack Gas Exit Temperature Range (^{o}F)**
22 (3 stacks)	33-36	10-24	1834-2752	68-70
23 (59 stacks)	44-50	3-24	571-7934	68-70
24 (10 stacks)	32-43	5-34	432-3669	68-70

Table 7 Key:
EU# = Emission Unit Number
^{o}F = Degree Fahrenheit

5. GENERAL CONDITIONS

The Permittee is subject to, and shall comply with, the following general conditions:

A. Pursuant to 310 CMR 7.01, 7.02, 7.09 and 7.10, should any nuisance condition(s), including but not limited to smoke, dust, odor or noise, occur as the result of the operation of the Facility, then the Permittee shall immediately take appropriate steps including shutdown, if necessary, to abate said nuisance condition(s).

B. If asbestos remediation/removal will occur as a result of the approved construction, reconstruction, or alteration of this Facility, the Permittee shall ensure that all removal/remediation of asbestos shall be done in accordance with 310 CMR 7.15 in its entirety and 310 CMR 4.00.

C. If construction or demolition of an industrial, commercial or institutional building will occur as a result of the approved construction, reconstruction, or alteration of this Facility, the Permittee shall ensure that said construction or demolition shall be done in accordance with 310 CMR 7.09(2) and 310 CMR 4.00.

D. Pursuant to 310 CMR 7.01(2)(b) and 7.02(7)(b), the Permittee shall allow MassDEP and / or USEPA personnel access to the Facility, buildings, and all pertinent records for the purpose of making inspections and surveys, collecting samples, obtaining data, and reviewing records.

E. This Plan Approval does not negate the responsibility of the Permittee to comply with any other applicable Federal, State, or local regulations now or in the future.

F. Should there be any differences between the Application and this Plan Approval, the Plan Approval shall govern.

G. Pursuant to 310 CMR 7.02(3)(k), MassDEP may revoke this Plan Approval if the construction work is not commenced within two years from the date of issuance of this Plan Approval, or if the construction work is suspended for one year or more.

H. This Plan Approval may be suspended, modified, or revoked by MassDEP if MassDEP determines that any condition or part of this Plan Approval is being violated.

I. This Plan Approval may be modified or amended when in the opinion of MassDEP such is necessary or appropriate to clarify the Plan Approval conditions or after consideration of a written request by the Permittee to amend the Plan Approval conditions.

J. The Permittee shall conduct emission testing, if requested by MassDEP, in accordance with USEPA Reference Test Methods and regulation 310 CMR 7.13. If required, a pretest

protocol report shall be submitted to MassDEP at least 30 days prior to emission testing and the final test results report shall be submitted within 45 days after emission testing.

K. Pursuant to 310 CMR 7.01(3) and 7.02(3)(f), the Permittee shall comply with all conditions contained in this Plan Approval. Should there be any differences between provisions contained in the General Conditions and provisions contained elsewhere in the Plan Approval, the latter shall govern.

6. MASSACHUSETTS ENVIRONMENTAL POLICY ACT

MassDEP has determined that the filing of an Environmental Notification Form (ENF) with the Secretary of Energy & Environmental Affairs, for air quality control purposes, was not required prior to this action by MassDEP. Notwithstanding this determination, the Massachusetts Environmental Policy Act (MEPA) and 301 CMR 11.00, Section 11.04, provide certain "Fail-Safe Provisions," which allow the Secretary to require the filing of an ENF and/or an Environmental Impact Report (EIR) at a later time.

7. APPEAL PROCESS

This Plan Approval is an action of MassDEP. If you are aggrieved by this action, you may request an adjudicatory hearing. A request for a hearing must be made in writing and postmarked within twenty-one (21) days of the date of issuance of this Plan Approval.

Under 310 CMR 1.01(6)(b), the request must state clearly and concisely the facts, which are the grounds for the request, and the relief sought. Additionally, the request must state why the Plan Approval is not consistent with applicable laws and regulations.

The hearing request along with a valid check payable to the Commonwealth of Massachusetts in the amount of one hundred dollars ($100.00) must be mailed to:

Commonwealth of Massachusetts
Department of Environmental Protection
P.O. Box 4062
Boston, MA 02211

This request will be dismissed if the filing fee is not paid, unless the appellant is exempt or granted a waiver as described below. The filing fee is not required if the appellant is a city or town (or municipal agency), county, or district of the Commonwealth of Massachusetts, or a municipal housing authority.

MassDEP may waive the adjudicatory hearing-filing fee for a person who shows that paying the fee will create an undue financial hardship. A person seeking a waiver must file, together with the hearing request as provided above, an affidavit setting forth the facts believed to support the claim of undue financial hardship.

Enclosed is a stamped approved copy of the application submittal.

Should you have any questions concerning this Plan Approval, please contact Peter Russell by telephone at (508) 946-2821, or in writing at the letterhead address.

Sincerely,

This final document copy is being provided to you electronically by the Department of Environmental Protection. A signed copy of this document is on file at the DEP office listed on the letterhead.

_____

Thomas Cushing
Permit Chief
Bureau of Air and Waste

Enclosure

ecc: Walpole Board of Health
Walpole Fire Department
Raymond Deane, Siemens
Melissa Kenerson, GZA GeoEnvironmental
MassDEP/Boston - Yi Tian
MassDEP/SERO - Maria Pinaud, Peter Russell